No. 90-45

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

HOFFMANN-LA ROCHE INC.,

Petitioner,

—v.—

UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF ALABAMA,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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QUESTIONS PRESENTED

(1) Whether, in approving the district court's refusal to conduct any balancing of interests under Fed. R. Civ. P. 26 in ordering disclosure of information confidentially disclosed to petitioner and the United States Food and Drug Administration ("FDA") by third party non-litigants, the Eleventh Circuit ignored the dictates of Rule 26 and placed itself in conflict with the decisions of other circuits, and the Eleventh Circuit itself.

(2) Whether the Eleventh Circuit's sanction of the district court's failure properly to apply Fed. R. Civ. P. 26 or to consider regulations of the FDA protecting the identities of third-party physicians who voluntarily submit adverse drug experience reports seriously jeopardizes the integrity of the FDA's Adverse Drug Experience Reporting System and, as a result, public health and safety.

(3) Whether the errors by the Eleventh Circuit set forth in (1) and (2) above demand summary reversal by this Court and the issuance of a writ of mandamus to correct the error by the district court.

LIST OF PARTIES

Petitioner is Hoffmann-La Roche Inc., a corporation organized and existing under the laws of New Jersey, with its principal place of business in Nutley, New Jersey, whose division, Roche Biomedical Laboratories, Inc., is a co-defendant in this action. The following are the other subsidiaries or affiliates of Hoffmann-La Roche Inc.: Roche Diagnostic Systems, Inc.; Hoffmann-La Roche Service Corp.; Hoffmann-La Roche Sciences, Inc.; Lab Delivery Service of New York City, Inc.; Medi-Physics, Inc.; Rorad, Inc.; Technad, Inc.; Cintichem, Inc.; Roche Professional Service Centers Inc.; Hoffmann-La Roche Enterprises, Inc.; Roche Medical Electronics Inc.; Hoffmann-La Roche Holdings Inc.; Analytics Laboratory Incorporated; Medical Laboratory Associates, Inc.; Sacramento Clinical Laboratory, Inc.; Columbus Pathology Laboratory, Inc.; Kontron Electronics Incorporated; and The Hoffmann-La Roche Foundation.

Respondent is the United States District Court for the Northern District of Alabama, Honorable Seybourn H. Lynne, District Judge.

Plaintiffs and respondent real parties in interest are Jimmy S. Durham, and his parents Jerry W. Durham and Judy C. Durham, who sue for themselves and for the use and benefit of Provident Life & Accident Insurance Company and Blue Cross/Blue Shield of Tennessee.

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Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

TO: The Honorable, the Chief Justice and Associate Justices of the Supreme Court of the United States:

Hoffmann-La Roche Inc., the petitioner herein, prays that this Court issue a writ of certiorari and summarily reverse the judgment of the United States Court of Appeals for the Eleventh Circuit entered in the above-captioned case on February 2, 1990.

OPINIONS BELOW

The order of the Eleventh Circuit denying petitioner's application for a writ of mandamus (over the dissent of Judge Clark) to correct an order of the U.S. District Court for the Northern District of Alabama is unreported and is printed in Appendix A hereto. The order of the U.S. District

Court for the Northern District of Alabama dated July 13, 1989 is unreported and is printed in Appendix B hereto.

JURISDICTION

The judgment of the Eleventh Circuit (Appendix A, *infra*) was entered on February 2, 1990. A timely petition for rehearing and suggestion of rehearing in banc was denied on May 1, 1990. The jurisdiction of the Supreme Court is invoked pursuant to 28 U.S.C. § 1254(1).

Statutory Provisions Involved

Rule 26(c) of the Federal Rules of Civil Procedure provides in relevant part:

> (c) **Protective Orders.** Upon motion by a party or by the person from whom discovery is sought, and for good cause shown, the court in which the action is pending . . . may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following: (1) that the discovery not be had; (2) that the discovery may be had only on specified terms and conditions, including a designation of the time or place; (3) that the discovery may be had only by a method of discovery other than that selected by the party seeking discovery; (4) that certain matters not be inquired into, or that the scope of the discovery be limited to certain matters; (5) that discovery be conducted with no one present except persons designated by the court. . . . (7) that a trade secret or other confidential research, development, or commercial information not be disclosed or be disclosed only in a designated way. . . .
>
> If the motion for a protective order is denied in whole or in part, the court may, on such terms and conditions

as are just, order that any party or person provide or permit discovery. . . .

The All Writs Statute, 28 U.S.C. § 1651(a), provides that the "Supreme Court and all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law."

Title 21 of the Code of Federal Regulations § 314.80 provides in relevant part:

> § 314.80 **Postmarketing reporting of adverse drug experiences** [by pharmaceutical manufacturers]
>
> . . .
>
> (h) *Patient privacy.* An applicant should not include in [adverse reaction reports] the names and addresses of individual patients. . . . The applicant should include the name of the reporter from whom the information was received. Names of patients, health care professionals, hospitals, and geographical identifiers in adverse drug experience reports are not releasable to the public under FDA's public information regulations in Part 20.
>
> . . .

Title 21 of the Code of Federal Regulations § 20.111 provides in relevant part:

> § **20.111 Data and information submitted voluntarily to the Food and Drug Administration.**
>
> (a) The provisions of this section shall apply only to data and information submitted voluntarily to the Food and Drug Administration, whether in the course of a factory inspection or at any other time, and not as a part of any petition, application, master file, or other required submission or request for action. Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of

this section and will be handled as if they had been required to be submitted.

. . .

(c) The following data and information submitted voluntarily to the Food and Drug Administration are available for public disclosure unless extraordinary circumstances are shown:

. . .

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be disclosed as follows:

(i) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and other information that would identify the person submitting the information.

(ii) If submitted by the manufacturer of the product, the record is available for public disclosure after deletion of:

. . .

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

. . .

(iii) If submitted by a third party, such as a physician or hospital or other institution, the record is available for public disclosure after deletion of:

. . .

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

. . .

STATEMENT OF THE CASE

Preliminary Statement

This petition presents for review the propriety of the Eleventh Circuit's order (over the dissent of Judge Clark) denying a writ of mandamus to correct an order of the United States District Court for the Northern District of Alabama. The trial court's order compelled production to plaintiffs Jimmy S. Durham, et al. ("plaintiffs") of the identities of third party physicians who voluntarily submitted adverse drug experience reports ("ADRs") to petitioner.

In ordering the production of this confidential identifying information, the district court failed to follow the simplest dictates of law. It did not engage in any balancing of the interests of persons affected by its order as required by Rule 26. This error was grievous not only because plaintiffs' need for this discovery is slight to nonexistent, but also because of important public policies in nondisclosure that were ignored by the district court, but that are squarely set forth in relevant FDA regulations that protect the identity of physicians who voluntarily submit ADRs.

The Eleventh Circuit's order sanctioned the district court's action in bypassing the dictates of Rule 26 and sanctioned as well the district court's failure to consider any reasonable alternatives to wholesale production of the names of the reporting physicians. These errors not only jeopardize the integrity of the FDA's adverse drug experience reporting system but also constitute clear errors of law that demand summary correction by this Court.

The Rulings Below

Petitioner is the defendant in a product liability action pending in the United States District Court for the Northern District of Alabama, *Durham v. Hoffmann-La Roche, Inc.*, Civ. Action No. CV 89-L-0075-S. In that action, plaintiffs seek damages for psychiatric injury allegedly arising out of use of the prescription drug Accutane, which is manufactured

by petitioner and which was prescribed for use by plaintiff Jimmy S. Durham by his physician.

On or about December 14, 1988, plaintiffs sought discovery from petitioner of, among other things, ADRs regarding Accutane and "depression." These reports by petitioner to the FDA are based upon data voluntarily submitted to petitioner by physicians throughout the nation who report their adverse experiences with Accutane on the understanding that their names, and those of their patients, will be kept fully confidential. Protection against disclosure of the names of such physicians and their patients is specifically provided for in FDA regulations.

On April 7, 1989, petitioner agreed to provide plaintiffs with the complete adverse experience reports, redacting only information identifying the reporting physicians and their patients. On or about July 3, 1989, plaintiffs moved to compel production of the identities of the reporting physicians and, on July 13, 1989, the Honorable Seybourn H. Lynne, United States District Judge, ordered such production.

On November 7, 1989, Judge Lynne denied Petitioner's motion to reconsider this ruling and on December 1, 1989, Judge Lynne granted petitioner's motion to stay his order pending a determination by the United States Court for Appeals for the Eleventh Circuit of petitioner's request for a writ of mandamus.

Petitioner's request for a writ of mandamus was filed on December 8, 1989. On February 2, 1990, the petition was denied without opinion by a panel of the Eleventh Circuit (Tjoflat, CJ., Johnson, Clark, J.J.). In dissenting from that ruling, Judge Clark argued that the district court's failure to engage in any balancing of interests and its failure to adopt certain obvious alternatives to wholesale disclosure of the identities of all the third-party physicians constituted clear error, which was correctible by mandamus.

On February 22, 1990, petitioner filed a timely Petition for Rehearing and Suggestion of Rehearing in Banc, which the

Eleventh Circuit denied on May 1, 1990. On May 9, 1990, petitioner filed in the Eleventh Circuit a Motion to Stay Mandate Pending Application for Certiorari. On June 7, 1990 the Eleventh Circuit granted petitioner's motion for a recall and stay of the mandate pending application for certiorari. The instant petition for a writ of certiorari is filed within 90 days from May 1, 1990, Sup. Ct. R. 13.4, and therefore is timely.

The Adverse Drug Experience Reporting System

Plaintiffs seek the names of physicians who have advised petitioner in confidence about their patients' adverse experiences with petitioner's product Accutane. These physicians are all non-parties to this action and their names are contained in ADRs filed by petitioner with the FDA. These ADRs—and physicians' voluntary cooperation in their compilation—are the lynchpin of the FDA's system for monitoring the safety of drugs in this country.

Voluntary reports by physicians to pharmaceutical companies and to FDA provide the basis for investigation of adverse experiences, reports to FDA, warnings to physicians, changes in prescribing information and the like that are critical to the safe use of pharmaceuticals in this country. Without voluntary reports by the physicians, neither the manufacturer nor FDA can be sure it will learn about adverse experiences with marketed drugs. 39 Fed. Reg. 44629 (Dec. 24, 1974).

FDA has recognized that its reporting system depends upon the voluntary cooperation of physicians and that, for the system to work, the physicians' names must be kept confidential. In promulgating regulations for disclosure of ADRs following enactment of the Freedom of Information Act ("FOIA"), FDA acknowledged that physicians would not voluntarily reveal adverse drug information to FDA unless their identities were kept confidential:

> Experience during the past two years has shown that . . . physicians are uniformly unwilling to divulge consumer complaint or adverse reaction information, or

> other materials of this type, voluntarily except on a pledge of confidentiality.

39 Fed. Reg. 44628 (December 24, 1974). For that reason, FDA determined that voluntary reports of adverse reactions made by physicians to FDA "will be made public [only] after all identifying information relating to the patient, physician and institution has been deleted, . . ." *Id.*

FDA reached the same conclusion with respect to voluntary reports by physicians to drug manufacturers, which the manufacturers are required to report to FDA in the form of ADRs. By regulation, the FDA has explicitly made the promise of confidentiality applicable to *any* identifying information relating to physicians (and other health care professionals) that is included in ADRs submitted by the manufacturer to FDA. 21 C.F.R. § 314.80(h).

FDA reached this policy judgment with full knowledge that such identifying data is often eagerly sought by plaintiff's counsel in product liability lawsuits such as this one.

> Large numbers of requests are received from plaintiff's attorneys in product liability lawsuits, requesting records relating to any other injuries caused by the product that is the subject of the lawsuit.

39 Fed. Reg. 44629 (December 24, 1974). These claims are insufficient to override the public interest in protecting the confidentiality of reporting physicians. FDA will release ADRs to plaintiffs in product liability actions *only* "with identifying information deleted." *Id.*

Thus, for overriding reasons of public health, the Accutane ADRs at issue in this case are obtainable from FDA only with the names of the reporting physicians deleted. Plaintiffs have sought to evade FDA's public health determination by seeking directly from petitioner information that they cannot obtain from FDA. In what Judge Clark recognized was a clear abuse of discretion, the trial court has abetted plaintiffs' end run on public policy by ordering petitioner to disclose this confidential information in wholesale and unrestricted fashion.

REASONS FOR GRANTING THE WRIT

I. The Eleventh Circuit's Order Is in Conflict With the Decisions of All Other Circuits as Well As Decisions of the Eleventh Circuit Itself

Petitioner has produced to plaintiffs over one hundred ADRs concerning Accutane and depression. In ordering the disclosure of the name of *every* non-party physician who voluntarily submitted such a report to petitioner, the district court gave *no* weight to the public interest favoring the confidentiality of such reporting. The trial court's refusal to balance the interests of the public and the respective parties was a clear error of law. No court has ever ruled that a Rule 26 motion can be resolved without a balancing of relevant interests.

Indeed, the result below is in direct conflict with the decisions of *every* Circuit Court of Appeals—including the Eleventh Circuit itself. *See, e.g., Mack v. Great Atlantic & Pacific Tea Co.*, 871 F.2d 179, 187 (1st Cir. 1989); *United States v. Arthur Young & Co.*, 677 F.2d 211, 219 (2d Cir. 1982), *aff'd in part, rev'd in part on other grounds*, 465 U.S. 805, *cert. denied*, 466 U.S. 936 (1984); *Smith v. BIC Corp.*, 869 F.2d 194, 199 (3d Cir. 1989); *Keyes v. Lenoir Rhyne College*, 552 F.2d 579, 581 (4th Cir.), *cert. denied*, 434 U.S. 904 (1977); *In re International Systems & Controls Corp.*, 693 F.2d 1235, 1240-41 (5th Cir. 1982); *The Courier-Journal v. Marshall*, 828 F.2d 361, 364 (6th Cir. 1987); *Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 559 (7th Cir. 1984); *General Dynamics Corp. v. Selb Manuf. Co.*, 481 F.2d 1204, 1212 (8th Cir. 1973), *cert. denied*, 414 U.S. 1162 (1974); *Munoz-Santana v. INS*, 742 F.2d 561, 562-64 (9th Cir. 1984); *Centurion Indus., Inc. v. Warren Steurer & Assocs.*, 665 F.2d 323, 325 (10th Cir. 1981); *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985); *Heat & Control, Inc. v. Hester Industries, Inc.*, 785 F.2d 1017, 1023-24 (Fed. Cir. 1986); *In re Sealed Case*, 856 F.2d 268, 272 (D.C. Cir. 1988).

These uniform decisions hold that where the parties have a dispute regarding discovery, Rule 26 obligates a district court to balance the requesting party's interest in obtaining the evidence sought against the harm to the party opposing discovery and others of such disclosure. This mandatory balancing was not performed by the district court in this case.

Farnsworth was a case remarkably like this one. Procter & Gamble ("P&G"), defendant in a variety of product liability cases involving toxic shock syndrome, sought discovery from the Center for Disease Control ("Center") of all data relating to its study of the disease. Although the Center provided substantial discovery to P&G, it refused to release the names of women who had voluntarily provided the Center with details about their illness. It argued, as petitioner does here, that disclosure of the names "could seriously damage this voluntary reporting." 785 F.2d at 1547. Balancing this important interest in confidentiality against the substantial evidence already available to P&G, the district court quashed the subpoena, *Farnsworth v. Procter & Gamble Co.*, 101 F.R.D. 355 (N.D. Ga. 1984).

The Eleventh Circuit affirmed. In so doing, the court made explicit that the trial court's *duty* is to exercise its discretion, that is, to balance the competing interests of the parties rather than simply to order discovery because the material was arguably relevant.

> While Rule 26(c) articulates a single standard for ruling on a protective order motion, that of "good cause," the federal courts have superimposed a somewhat more demanding balancing of interests approach to the Rule. Under that standard, *the district court's duty was to balance P & G's interest in obtaining the names and addresses of the study participants against the Center's interest in keeping that information confidential.*

785 F.2d at 1547 (citations omitted; emphasis added).[1]

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1 *See also Solarex Corp. v. Arco Solar, Inc.*, 121 F.R.D. 163, 169-70 (E.D.N.Y. 1988), *aff'd*, 870 F.2d 642 (Fed. Cir. 1989); *Apicella v. McNeil Laboratories, Inc.*, 66 F.R.D. 78, 82 (E.D.N.Y. 1975).

Similarly, in *Deitchman*, the Seventh Circuit vacated and remanded a district court's order on the ground that the district court had failed properly to consider the competing hardships of the requested discovery and had failed to consider the possibility of fashioning a protective order that would have provided the requesting party with relevant information while at the same time protected third parties against the loss of confidential information. 740 F.2d at 563-64. *See also Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1024-26 (Fed. Cir. 1986) (vacating and remanding district court order mandating the disclosure of, inter alia, trade secrets, on the ground that the district court had failed to balance the relevance of the discovery sought against the potential hardship that allowing discovery could impose, and had failed to fashion an order which balanced the parties' competing interests).

Under these and similar cases, the district court was obliged to balance the plaintiffs' interest in obtaining the names of the reporting physicians against the interests of petitioner, the FDA and the public in keeping that information confidential. The trial court wholly abrogated that duty. It engaged in *no* balancing of interests and instead ordered wholesale disclosure of the name of *every* reporting physician. This was a clear error of law and, indeed, a usurpation of judicial power. *See, e.g., In re Sealed Case, supra*, 856 F.2d at 272 (where district court's order did not show "engagement in this essential balancing process . . . the failure to balance at all requires remand to the District Court to consider the respective interests" of the affected parties). In sanctioning that clear error, the panel majority was likewise in error and has created a conflict in the decisions of the United States Courts of Appeals generally (and even within the Eleventh Circuit itself).

II. The Eleventh Circuit's Order Jeopardizes Important Public Health and Safety Considerations

The trial court's failure to engage in the balancing of interests required by Rule 26 and the relevant caselaw is particu-

larly unfortunate because under *any* fair balancing of interests, petitioner's motion for a protective order should have been granted. The denial of that motion was a clear abuse of discretion and the refusal of the panel majority to correct that abuse was in error. Because the decision below ignored important questions of public health and, if not corrected, would cripple the FDA's voluntary reporting system for adverse drug reactions, this case presents questions of substantial importance that mandate summary reversal of the decision below.

A. The Public Interest in Confidentiality

There can be no legitimate dispute about the substantial public interest in keeping confidential the names of physicians who voluntarily report their patients' adverse experiences with a prescription drug. Indeed, other than the court below, *every court* that has addressed the issue has found that the legitimate need for confidentiality outweighs the purposes of any individual litigant. *See Harris v. Upjohn Co.*, 115 F.R.D. 191, 192 (S.D. Ill. 1987) ("release of the names of physicians who communicated to [pharmaceutical company] would be against public policy"); *Wesley v. Rye*, 490 So.2d 272, 272 (La.), *reh'g denied*, 492 So.2d 1210 (1986) (names of physician on drug experience reports ordered deleted); *Stahl v. Rhee*, 136 A.D.2d 539, 540, 523 N.Y.S.2d 159, 161 (2d Dep't 1988) ("drug experience reports [submitted to manufacturers] are an important component of the Food and Drug Administration's voluntary reporting procedure, and revealing such identities could compromise this beneficial endeavor"); *Newsom v. Breon Laboratories, Inc.*, 709 S.W.2d 559, 560 (Tenn. 1986) ("disclosure of the identity of doctors will inhibit the effectiveness of the voluntary reporting system that [FDA] and the drug industry rely upon").

Indeed, it is precisely because of the public interest in confidentiality that FDA submitted a letter in support of petitioner's position here. *See* Appendix C, hereto. Upon learning of the district court's order in this case, FDA wrote

to petitioner's counsel confirming that petitioner's position was "consistent with regulations promulgated by [FDA] governing FDA's release of information contained in adverse drug experience reports." FDA explained, as petitioner has argued, that it is concerned "that the disclosure of the names of physicians who voluntarily submit adverse drug experience information may deter such disclosure, thereby jeopardizing the current system of adverse drug experience reporting." In FDA's view, the system "rests upon the voluntary cooperation of physicians" and "[w]ithout that cooperation, the system breaks down." *Id.* at pp. 7a-8a.

Thus, FDA fully recognizes that, although the manufacturer may be required to report adverse experiences to the FDA, the manufacturer must

> rely upon physicians [voluntarily] to make adverse drug experience reports to them. If physicians do not, in the first instance, report to the drug manufacturers their adverse drug experiences, those manufacturers will have little to report to FDA. *Id.* at p. 8a.

And if the "free and uninhibited flow of information among patients, physicians, drug companies and FDA" is diminished, then the "FDA's ability to fulfill its mission to protect the public health is compromised." Orders such as that entered by the trial court below have "the potential to 'chill' the free flow of information among physicians, drug manufacturers and FDA." *Id.* at pp. 7a, 9a.

The reason for FDA's concern is clear. Plaintiffs have made no secret of their plans. If the discovery is allowed, they intend to contact the reporting physicians—non-parties to this litigation—and seek information about their experiences with Accutane. Thus, non-party physicians who for public-spirited reasons have voluntarily reported potential adverse experiences with Accutane will be subjected to inquiry, and possible deposition, from plaintiffs in this case.

But that will not be the end of the matter. The non-party physicians whose discovery plaintiffs seek have knowledge

about Accutane, not about the facts of this case. If orders such as the one in dispute become routine, such physicians will be subject to repeated inquiry and possible deposition in case after case. The "potential for abuse is great, especially since no finality accrues and no statute of limitations runs to protect the [physician] who has relevant information." *In re Snyder*, 115 F.R.D. 211, 216 (D. Ariz. 1987). *See also Kaufman v. Edelstein*, 539 F.2d 811, 821 (2d Cir. 1976).

Precisely to avoid this result, physicians would be deterred from reporting their adverse experiences to the manufacturer, and the public would be the loser. As FDA put it in supporting petitioner's position here,

> If courts require drug companies involved in litigation to disclose the names of physicians who report adverse drug experiences, and thereby subject reporting physicians to probing inquiries from attorneys, and possible involvement in litigation, physicians will likely become reluctant to report such information. App. C. at pp. 8a-9a.

B. Plaintiffs Have Little or No Need for the Information

The balancing mandated by Rule 26 includes an assessment not only of the need for confidentiality, but also of respondents' legitimate interests in discovery. The district court did not assess these interests and, indeed, plaintiffs proffered little to support their demands. Upon analysis, plaintiffs' need for the identity of the reporting physicians is slight to nonexistent and, under any balancing, insufficient to outweigh the public interest in keeping the information confidential.

As the Eleventh Circuit recognized in *Farnsworth*, any assessment of the need for the additional discovery begins with a review of the discovery that has already been afforded. In this regard, petitioner has literally emptied its files. With the exception of identifying information about the reporting physicians and their patients, plaintiffs have been given access to everything that petitioner knows about the alleged association between Accutane and depression. Peti-

tioner's New Drug Application ("NDA"), comprising over 300,000 pages and containing the evidence of which petitioner is aware bearing on Accutane's efficacy and safety, has been made available to plaintiffs for their inspection. The NDA contains not only all the information available to petitioner as of the time of Accutane's approval by FDA, including its extensive pre-marketing study of the drug's safety and efficacy, but also supplemental information required by FDA to be filed on an ongoing basis. In particular, this includes reports of all adverse experiences with the drug reported to petitioner by any source.

Moreover, petitioner has produced the ADRs themselves. It has provided to plaintiffs over 100 reports of adverse experiences with Accutane involving alleged depression. The reports have been redacted to delete the identifying information at issue here. But in all other respects, they are complete. And they provide detailed information about all the patient histories that are arguably relevant to this case.

Plaintiffs contend that they need the names of the physicians in order to acquire *additional* detail about these adverse reactions. But there is no good reason to believe that further discovery of the reporting physicians would lead to any additional relevant facts. The physician has every interest to include all relevant data in the adverse experience report and petitioner has every interest to solicit such information in responding to the report. The physician is interested in treating his or her patient and seeks to provide the manufacturer with all relevant data so as to respond to the patient's problem. And petitioner has a legal and ethical responsibility to respond in as complete and accurate a fashion as possible. There is no reason in experience or logic to assume that any relevant data has been omitted from the ADRs and that further discovery from the physicians themselves will yield anything of value to plaintiffs' case.

In short, the probative value of further discovery from non-party physicians is slender and it cannot, under any balancing of competing values, overcome the serious harm to

the nation's adverse experience reporting system that would follow from the trial judge's order. For this reason, Judge Clark correctly concluded that petitioner should be permitted to redact the physicians' names from the ADRs and that further discovery should be permitted *only if* (1) "such information is required to resolve disputed issues of fact between the parties" *and* (2) "such information is in no other way available to the plaintiffs." Because plaintiffs have not remotely approached such a showing—nor can they—the trial judge's order of wholesale disclosure was a gross abuse of discretion that, unless corrected, will cause serious injury to the public interest.

III. Summary Reversal and Mandamus is Appropriate

The issues raised in this petition are not only important, they are also simple and easily resolved. Where, as here, the decision below is clearly erroneous, summary reversal by this Court and the issuance of a writ of mandamus is appropriate.

A. The Court Should Grant Summary Reversal in Light of the Clearly Erroneous Decision of the Court Below

In view of the clear error of the decision below, and its conflict with other circuit court decisions, summary reversal is warranted here. Sup. Ct. R. 23.1. A summary disposition would be an appropriate use of the Court's power to grant certiorari and reverse the decision of the court of appeals below in the interest of justice. 28 U.S.C. § 2106 (1982); *Petite v. United States*, 361 U.S. 529, 539 (1960).

The main function of summary reversal is to correct the sort of clearly erroneous decisions that both the Eleventh Circuit and the district court below rendered in the present case. The issues presented here are important and justify the Court's review by way of a grant of certiorari; they nevertheless warrant summary disposition in favor of petitioner

because they are not difficult enough to necessitate full briefing and oral argument.

Summary reversals share features in common with writs of mandamus. The standard governing a grant of a writ of mandamus is that the decision must be in clear error as a matter of law. Mandamus is, moreover, an appropriate means of reviewing erroneous orders compelling the discovery of privileged information. *Harper & Row Publishers, Inc. v. Decker*, 423 F.2d 487, 492 (7th Cir. 1970), *aff'd*, 400 U.S. 348 (1971) (mandamus is appropriate to prevent disclosure of privileged communication). The clearly erroneous standard has been met in this case, and also forms sufficient ground for summary reversal.

In recent years, this Court has granted summary reversal where the court below has deviated from settled principles of law. *EEOC v. FLRA*, 476 U.S. 19, 26 n.5 (1986) (Stevens, J., dissenting). Thus, summary reversal has been granted in cases where either past precedent or statutory law "obviously compel a contrary conclusion" from that reached by the lower court. *Rhodes v. Stewart*, 488 U.S. 1, 109 S. Ct. 202, 205 (1988) (Blackmun, J., dissenting); *see also Pennsylvania v. Bruder*, 488 U.S. 9 (1988) (reversing state court judgment deemed contrary to established Supreme Court precedent governing case). This situation more often arises when, as here, the "plain language" of the rule at issue is found to be "so compelling" that it would be unjust for the Court not to correct a decision that resulted from the statute's misinterpretation. *INS v. Hector*, 479 U.S. 85, 87 (1986).

This case is clearly appropriate for summary disposition. First, the law concerning the requisite balancing under Rule 26 "is settled and stable." *Schweiker v. Hansen*, 450 U.S. 785, 791 (1981) (Marshall, J., dissenting). Second, "the facts are not in dispute." *Id.* And finally, "the decision below is clearly in error." *Id.* The Court requires no more to dispose of this case by summary reversal.

B. Mandamus is Appropriate

This Court has recognized the "vital corrective and didactic function" of mandamus, *Will v. United States*, 389 U.S. 90, 107 (1967). Mandamus may be used as a means of immediate appellate review of orders compelling the production of documents claimed to be protected by privilege or other interests of confidentiality. *See In re Fink*, 876 F.2d 84, 84 (11th Cir. 1989) (mandamus appropriate to review discovery order concerning privileged information because effective review is difficult once the material has been made public); *Bogosian v. Gulf Oil Co.*, 738 F.2d 587, 591 (3d Cir. 1984); *Iowa Beef Processors, Inc. v. Bagley*, 601 F.2d 949, 953-54 (8th Cir.), *cert. denied*, 441 U.S. 907 (1979). Moreover, every Circuit that has addressed the issue has held that mandamus is an appropriate means of reviewing erroneous orders compelling the discovery of privileged information.[2]

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2 *E.g.*, *In re Claus Von Bulow*, 828 F.2d 94, 97-99 (2d Cir. 1987) (mandamus properly lies to review district court's discovery order which order raises important question regarding attorney-client privilege and client has no other adequate remedy available); *Bogosian v. Gulf Oil Corp.*, 738 F.2d 587, 591 (3d Cir. 1984) (mandamus may properly be used as means of immediate appellate review of orders compelling production of documents claimed to be protected by privilege or other interests in confidentiality); *Rowley v. McMillan*, 502 F.2d 1326, 1335 (4th Cir. 1974) (mandamus is appropriate method of obtaining review of district court's discovery order regarding production of privileged documents); *In re Burlington Northern, Inc.*, 822 F.2d 518, 522 (5th Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988) (mandamus review is appropriate where district court's order directs production of documents for which attorney-client privilege and work product immunity have been asseerted); *Harper & Row Publishers, Inc. v. Decker*, 423 F.2d 487, 492 (7th Cir. 1970), *aff'd*, 400 U.S. 348 (1971) (mandamus is appropriate to prevent disclosure of privileged communication); *In re Chrysler Motors Corp. Overnight Evaluation Program Litigation*, 860 F.2d 844, 846 (8th Cir. 1988) (mandamus is proper means to challenge a production order on grounds of attorney work-product privilege); *Admiral Ins. Co. v. United States Dist. Ct. for the Dist. of Arizona*, 881 F.2d 1486, 1491 (9th Cir. 1989) (mandamus is appropriate remedy to review orders compelling discovery in face of assertions of privilege); *Jenkins v. Weinshienk*, 670 F.2d 915,

The use of mandamus is particularly appropriate when the asserted privilege is important, an adequate alternative method of obtaining review is lacking, and the harm resulting from a disclosure of privileged information is serious. *In re Burlington Northern, Inc.*, 822 F.2d 518 (5th Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988); *see Suarez-Valdez v. Shearson Lehman/American Express, Inc.*, 858 F.2d 648 (11th Cir. 1988). Mandamus is proper in this case because of "the importance of the privilege, the seriousness of the injury if discovery is obtained, and the difficulty of obtaining effective review once the privileged information has been made public." *In re Fink*, *supra*, 876 F.2d at 84; *see In re Burlington Northern, Inc.*, *supra*, 822 F.2d at 522.

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917 (10th Cir. 1982) (exercies of mandamus power is appropriate when district court orders production of information over litigant's claim of privilege not to disclose).

CONCLUSION

For the foregoing reasons, Hoffmann-La Roche Inc.'s petition for a writ of certiorari should be granted.

Dated: July 3, 1990.

Respectfully submitted,

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APPENDICES

Appendix A

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 89-7896

Filed February 2, 1990

IN RE:

HOFFMAN-LAROCHE, INC.,

Petitioner.

On Petition for Writ of Mandamus to the
United States District Court for the
Northern District of Alabama

Before:

TJOFLAT, *Chief Judge*,
JOHNSON and CLARK, *Circuit Judges*.

BY THE COURT:

The petition for writ of mandamus is DENIED.

CLARK, *Circuit Judge*, dissenting:

It is my view that the petition for the writ of mandamus should be granted and the district court required to apply the balancing test applied by our court in *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545 (11th Cir. 1985):

> While Rule 26(c) articulates a single standard for ruling on a protective order motion, that of "good cause," the federal courts have superimposed a somewhat more demanding balancing of interests approach to the Rule.

> Under that standard, the district court's duty was to balance P & G's interest in obtaining the names and addresses of the study participants against the Center's interest in keeping that information confidential.

758 F.2d at 1547 (citations omitted).

In this lawsuit the Durhams, plaintiffs below and respondents herein, commenced this action against Hoffman-LaRoche, Inc., for damages resulting from injuries sustained by Jimmy S. Durham as a result of his ingestion of the prescription drug Accutane.

A dispute with respect to discovery arose when the defendant refused to produce adverse experience reports which are voluntarily submitted to the drug manufacturer by physicians prescribing and patients using Accutane. Drug manufacturers are required to submit certain of these reports to the United States Food and Drug Administration (FDA) pursuant to 21 C.F.R. § 314.80(c). Defendant agreed to submit to plaintiffs' counsel the adverse experience reports under the conditions that the names of the doctors and their patients be redacted from the reports.

Plaintiffs filed a motion to compel the documents and the district court entered an order which compelled the production of the reports with the patients' names redacted but permitted disclosure of the names of the physicians. Defendant then submitted the documents with the patients' and physicians' names redacted.

The defendant filed this petition for writ of mandamus. In our case of *In re Fink*, 876 F.2d 84 (11th Cir. 1989), we held that mandamus is an appropriate method for review of a discovery order which might compromise a claim of privilege or invade privacy rights since it is difficult to review effectively such an order once the information has been made public. We further held that in a diversity action, state law governs our consideration of such petitions.

The law of either Alabama or Tennessee governs this case, but which of these two cannot be made clear from the record. I have reviewed the law of both states and conclude that there are limitations upon disclosure of the type of informa-

tion sought here. *See Mull v. String*, 448 So.2d 952, 955 (Ala. 1984), and *Newsom v. Breon Laboratories*, 709 S.W.2d 559 (Tenn. 1986).

In *Newsom*, the trial court directed that all of the adverse experience reports be furnished to the plaintiffs with no deletions of physicians' or patients' names and addresses. The Supreme Court of Tennessee limited from the disclosure the names of both the patients and physicians, finding that no consideration had been given to the fact that the reporting doctors had reason to believe they had made the reports in confidence because the form issued by the FDA had the words "in confidence" on its face. The court also noted that the FDA's regulations provide that doctors' and patients' names are exempt from the disclosure requirements of the Freedom of Information Act. 21 C.F.R. § 20.111(c)(iii). Plaintiffs maintain that the disclosure limitations apply only to adverse reaction reports voluntarily submitted to the FDA. While the provision cited above applies to reports voluntarily submitted, nevertheless they misapprehend the law. *See* 21 C.F.R. § 314.80(h) (barring disclosure of names in required submission); 39 Fed.Reg. 44,615 (1974).

The court also found that the defendant in *Newsom*, as in this case, claimed that disclosure of the identity of the doctors would inhibit the effectiveness of the FDA's voluntary reporting system. The court then went on to provide that all of the reports with both physicians' and patients' names redacted should be furnished to the plaintiffs, after review of which the plaintiffs could select 12 of the reports in which they were most interested in knowing the names of the reporting physician. The trial court could then consider the plaintiffs' motion for discovery of those names and, if the plaintiffs could show good cause, the court should order the defendant to disclose the names to the clerk of the trial court to be kept under seal. The trial court would then direct the clerk to notify the 12 physicians that it had directed the defendant to reveal the names of the physicians to plaintiffs but that their names would not be revealed to any other persons without the respective physician's permission.

I would grant the writ of mandamus to permit the court to direct the defendant to furnish the reports with the names of the physicians redacted, as well as the patients, after which the district court would be free to order the defendant to produce the names of the physicians involved in some of the reports if the district court concluded that such information is required to resolve disputed issues of fact between parties and that such information is in no other way available to the plaintiffs.

Appendix B

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

CIVIL ACTION CV 89-L-0075-S

JIMMY S. DURHAM, JIMMY S. DURHAM, who sues by and through his father and next friend, JERRY W. DURHAM; JERRY W. DURHAM and JUDY C. DURHAM, who sue for themselves and for the use and benefit of PROVIDENT LIFE & ACCIDENT INSURANCE COMPANY and BLUE CROSS BLUE SHIELD OF TENNESSEE,

Plaintiffs,

vs.

HOFFMAN-LAROCHE, INC., a corp.; and ROCHE LABORATORIES, a Divisioin of Hoffman-Laroche, Inc.

Defendants.

ORDER TO COMPEL

The motion to compel discovery filed in behalf of plaintiffs on July 3, 1989, came on to be heard at the pretrial conference in the above-captioned action. Counsel for plaintiffs has requested that the documents described in the request for production of April 6, 1989, be produced within this district. At this time, the Court is inclined to require the production of such documents at defendants' place of business in Nutley, New Jersey, and has advised counsel that defendants will be required to ship such documents to this district only in the event counsel for plaintiffs experiences opposition and frustration in his effort to inspect and copy the requested documents in New Jersey.

Local counsel for defendants have agreed to accompany plaintiffs' attorney to defendants' place of business to render aid in identifying the documents sought.

With respect to plaintiffs' concern that defendants will insist on redacting the names and addresses of physicians and patients from adverse experience reports, the Court holds that only the names and addresses of patients may thus be redacted.

A protective order upon which counsel agree will be submitted to the Court for entry, and prior to inspection of such documents counsel for plaintiffs will not be required to sign a protective order designed only by defendants.

DONE this 12th day of July, 1989.

/s/ SEYBOURN H. LYNNE
Senior Judge

Appendix C

[LETTERHEAD, DEPARTMENT OF HEALTH & HUMAN SERVICES]

Office of the General Counsel
Food and Drug Division
Rockville, MD 20857

December 6, 1989

Karl E. Seib, Jr.
Patterson, Belknap, Webb & Tyler
Attorneys for Hoffmann-La Roche, Inc.
30 Rockefeller Plaza
New York, N.Y. 10112

Re: *Durham, etc. v. Hoffmann-La Roche, Inc., etc.*,
CV 89-L-0075-S (N.D. Ala. 1989).

Dear Mr. Seib:

I understand from you that your client, Hoffmann-La Roche, Inc. (Roche), has been ordered by the District Court for the Northern District of Alabama, Southern Division, to disclose the names and other identifying information of physicians making adverse drug experience reports. Roche is reluctant to disclose this information because it believes that such disclosure will discourage physicians from continuing to report adverse drug experience information to drug manufacturers, like Roche, in the future. Roche's view is consistent with regulations promulgated by the United States Food and Drug Administration (FDA) governing FDA's release of information contained in adverse drug experience reports.

In establishing its system of adverse drug experience reporting, one of FDA's primary concerns was to ensure the free and uninhibited flow of information among patients, physicians, drug companies and FDA. Without such a free and uninhibited flow of information, FDA's ability to fulfill its mission to protect the public health is compromised. Infor-

mation regarding the hazards attendant to drug use, both during the initial investigative stages and after, is necessary for FDA to fulfill its responsibility to protect the American public from unsafe drugs. *See* 39 Fed. Reg. 44629 (December 24, 1974).

FDA has previously stated its concern that the disclosure of the names of physicians who voluntarily submit adverse drug experience information may deter such disclosures, and thereby jeopardize the current system of adverse drug experience reporting. In the preamble to FDA's regulations providing for the public disclosure of certain information pursuant to the Freedom of Information Act (FOIA), FDA expressed this concern.

> Experience during the past 2 years has shown that manufacturers and physicians are uniformly unwilling to divulge consumer complaint or adverse reaction information, or other materials of this type, voluntarily except on a pledge of confidentiality.

39 Fed. Reg. 44628. FDA's FOIA regulations and its regulations establishing the adverse experience reporting system embody this concern. Those regulations preclude the disclosure by FDA of the names and other identifying information of reporting physicians. *See* 21 CFR 20.63(b), 20.111(c)(3), 314.80(h).

FDA's system of adverse drug experience reporting rests upon the voluntary cooperation of physicians. Without that cooperation, the system breaks down. FDA requires certain drug manufacturers to file with FDA information concerning adverse drug experiences. 21 CFR § 314.80. This information is intended to assist FDA in monitoring the safety of those drugs currently on the market. Drug manufacturers, in supplying this information to FDA, rely upon physicians to make adverse drug experience reports to them. If physicians do not, in the first instance, report to the drug manufacturers their adverse drug experiences, those manufacturers will have little to report to FDA. If courts require drug companies involved in litigation to disclose the names of physicians who report adverse drug experiences, and thereby subject report-

ing physicians to probing inquiries from attorneys, and possible involvement in litigation, physicians will likely become reluctant to report such information. Any conduct that has the potential to "chill" the free flow of information among physicians, drug manufacturers and FDA is not in the interest of public health and is, of course, of concern to FDA.

Sincerely yours,

/s/ CLAYTON H. PATERSON

Clayton H. Paterson,
Assistant Chief Counsel for Enforcement, Food and Drug Administration